

REVIEWING TRANSCUTANEOUS POWER SUPPLIES FOR HIGH POWER IMPLANTABLE HEART PUMPS

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ABSTRACT

This paper focuses on incorporating Transcutaneous Energy Transfer System (TETs) for medical implants which requires very high power, especially Total Artificial Heart (TAH) and Left Ventricular Assistant Devices (LVADs). These implants consume high power in the range 3 to 30W. So, these are conventionally powered using a percutaneous lead. This lead passes through the abdominal skin of a patient to connect to an external power supply. This skin area around the lead represents a source of potential infections and requires frequent treatment and surgery for replacing the leads. TET system can deliver power wirelessly and is widely in use for low power medical implants. Therefore, it gained immense interest to determine its suitability for high power implants. Thus, this paper presented a review of various commercial TAHs and LVADs and their power requirements. From the review, for high power implants, TET needs to overcome the limitations of the temperature variation of coils, impedance mismatch, and discontinuity in required power delivery. In the end, directions for future work are provided to fill these voids and to develop a TET system suitable for high power TAHs and LVADs.

KEYWORDS: Wireless Power Transfer, Artificial Heart & LVAD

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1. INTRODUCTION

In this paper review of high power medical implants: Left Ventricular Assistant Devices (LVADs) ^[1] and Total Artificial Heart (TAH) ^[2] and determines the challenges on incorporating transcutaneous energy transfer systems (TETs) as their power solutions are presented. An LVAD is a blood-pump implanted inside the patient's chest. Its role is to assist the heart in properly functioning its main pumping chamber, i. e., the left ventricle. ^[1,3] However, TAH replaces the native heart in all its functions and provide circulatory support to patients with both left and right ventricular in end-stage failure. ^[2, 4, 5] Initially they become first evident in the early 1930s, ^[6] when the Soviet scientist Vladimir Demikhov transplanted a total artificial heart to a dog. Since then, both LVAD and TAH are widely used as a bridge for transplantation or even for long-term treatment of ill patients. ^[7,8] However, due to the recent increase in a number of patients, these implants are increasingly being in-use for last few years to bridge the gap in finding suitable donor or meeting surgery waiting time for patient needed heart treatment. ^[8-11] Because of this demand, there have been significant developments in medical implants industry focusing on making LVADs and TAHs. ^[11] However, these devices are associated with many challenges in their design, development, and installation. For example, infection, size, device malfunction, power, battery replacement and compatibility of their material with blood and tissue. ^[11-17] Among these challenges, this paper is focused on powering these devices. ^[17-26] More specifically, both LVADs and TAHs require a power supply that is external to

the body of a patient. A percutaneous lead connects these devices to the external power source.^[21, 22] This lead starts from the internal pump and goes through the skin to an external power source. The area of contact between this driveline and the abdominal wall has reported a source of infections.^[21, 22] In addition, these devices are rated high power ($>3\text{W}$).^[16-22] Therefore, a constant power source is of prime importance. Recently, wireless power transfer (WPT) from the power source to a load across an air gap has successfully been used in various devices such as mobile phones^[23] and in medical devices such as pacemakers.^[24] However, these devices have low power requirements of the orders of tens of mill watts. Furthermore, WPT is associated with several challenges such as impedance mismatch,^[25, 26] heating of coils^[18] and continuous power supply.^[26] This becomes cumbersome for high power devices. Therefore, this paper presents the review of high power rated medical implants and the challenges of incorporating wireless power based transcutaneous energy transfer (TET)^[27] system to these systems.

2. TRANSCUTANEOUS ENERGY TRANSFER

Recently, the TET systems have gained significant attention as a solution to provide energy wirelessly to high power LVADs and TAHs.^[24-26] The basic block diagram of a TET power supply system is shown in Figure 1. It contains a power converter and a Transcutaneous transformer.

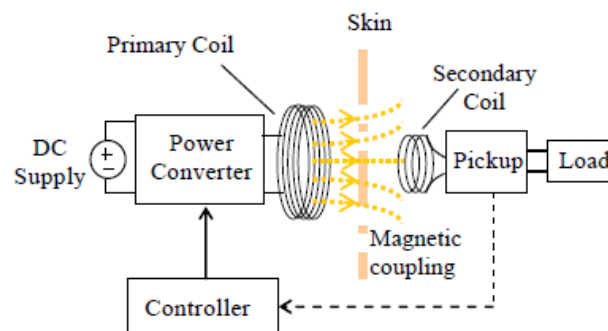


Figure 1: Basic Block diagram of the TET System

It is based on the principle of wireless power transfer.^[23] WPT has considerably been used in the medical industry^[21, 24] mobile phones,^[23] RFID and charging remote electronics such as windmill base. However, for LVADs and TAHs, the TET can transfer power through the skin without direct electrical connectivity.^[25] This helps to eliminate the percutaneous drivelines and therefore reduce the risk of infections.^[21, 22] In principle, a transcutaneous transformer is implemented with two coils separated by patient's skin^[21, 22] To drive this transformer (Figure 1), the TET system consists of a primary power converter, which uses the dc voltage as input and converts it to a high-frequency sinusoidal voltage.^[21, 22, 24] Because of this phenomenon, a magnetic field is produced around the primary coil and this results in an induced voltage in the secondary coil. The induced voltage is a sinusoidal voltage so this voltage is firstly rectified to dc voltage and then supplied to load such as LVAD and TAH. The input dc power source to the TET system (Figure 1) is placed externally. Therefore, the TET power system is proficient of long-term (theoretically infinite) functioning at high power outputs.

The efficiency of the TET system shown in Figure 1 highly depends upon the mutual inductance (M), coupling coefficient (k) and reflected impedance from the receiver to transmitter.^[25, 26] Mutual inductance represents the coupling link established between coils due to induced current in one of them in presence of a magnetic flux; i. e., when the two

coils are close to each other. The mutual inductance (M_{12}) of two coils is given by the double integral Neumann formula, [25,26] as:

$$M_{12} = \frac{\mu_0}{4\pi} \oint_{c_1} \oint_{c_2} \frac{ds_1 ds_2}{R_{12}} \quad (1)$$

Where μ_0 is permeability of free space, ds_1 and ds_2 represent elements of two coils, and R_{12} is the distance in magnitude from ds_1 and ds_2 . The second parameter, coupling coefficient, also specifies the relationship between two coils. [24, 25] It is a dimensionless number between 0 and 1, where '1' represents perfect coupling and '0' no interaction.

The coupling coefficient is defined as follows:

$$k_{12} = \frac{M_{12}}{\sqrt{L_p L_s}} \quad (2)$$

Where L_p and L_s is the self-inductance of primary and secondary coil respectively; and depends on the geometry of coils. For a TET system with high efficiency, high magnetic coupling between the coils is required. [21] This will result in low losses, high power transfer, and low tissue heat generation. However, at high coupling values close to 1, the third element (reflected impedance) plays an important role in the behavior of the primary tank circuit. It is because higher coupling implies higher reflected impedance from the receiver to the transmitter. This can cause a considerable drift of operating frequency or moves unstably between various operating frequencies. [21] Another important factor which affects the efficiency of the system is power loss resulting from the reactance of capacitors and inductors in both primary and secondary tank circuits. [21, 23, 24] This can be reduced by tuning the tank circuits to the resonance frequency. Thus, the operating frequency in a TET system is an important factor for consideration as it can affect the power efficiency, power transfer capacity, and physical size. [21, 23, 24] In a nutshell, the geometrical characterization of coils, operating frequency, and impedance match are the key factors in the design process of a TET system in order to reduce losses of the system.

The key applications of TET power supplies in medical implants are mentioned below:

2.1 Cochlear

It is implanted to patients with hearing problems. [28] Functioning of this device based on electrical impulses which are used to stimulate the auditory nerves inside the cochlea. For both power transmission and data communication, inductive coupling is used by Cochlear. Their power requirement is of the orders of 10mW and is generally operated in a frequency range of 1 to 10 MHz. The data transmission is done over the power link and its amount determines the operating frequency. Both external and internal coils are positioned above the ear. [28] These coils are approximately 30 mm in diameter and their separation ranges between 3 to 10 mm.

2.2 Cardiac Pacemaker

These pace-makers are mainly used when due to a malfunction, slower or missed heartbeat results in the natural heart. This pacemaker is implanted under the skin of the patient. It generates electrical pulses and these pulses simulate the heart. [20, 24, 29, 30, 31] A pulse generator is connected with electrodes and these electrodes are attached to the heart. Pulse generators have the microelectronic circuit and an implantable battery to power the pacemaker. The device operates in the power range of 30 to 100μW. [29, 30, 31] Pacemakers are usually charged through implanted Lithium-iodine batteries because of their low power consumption. [31] However, TET has also been introduced to power rechargeable

batteries in cardiac pacemakers. [24] The distance between the primary and secondary coils is approximately 5 to 15 mm and the range of diameter of coils is up to 40 mm.

2.3 Implantable Telemetry Unit

These units are used to monitor the biological signals in humans and animals. These signals contain electro-cardiograms, blood pressure, and body temperature. These telemetry units are basically used for wireless power transfer in two important areas. These areas are coupling of power and transmission of sensed data. [32, 33] The devices have power requirements of approximately 100 to 300mW.

2.4 Retinal Prosthetic Devices

Vision loss in patients is caused due to retinal pigmentosa and age-related degeneration. [34, 35] To restore the visual sensations inpatient, a retinal prosthetic device is used to stimulate retinal neurons electrically. For this purpose, a microelectrode array is used to stimulate the retina. In this case, the TET system is used for both power and bidirectional data transfer.[36, 37] Power requirement for these systems is up to 250mW and the distance between coils can vary between 7 – 15 mm.[36, 37]

2.5 Functional Electrical Simulators

This device is used to generate electrical stimulation to the paralyzed muscles and enables the partial restoration of the function of these muscles. It consists of an internal implanted electrode which generates the electrical stimulation. TET system provides the power to this electrode. These stimulators are also used as neuro simulation devices for spinal cord injury and head injuries. Power requirement for these electrical simulators is in the range of 100 mW to 1 W. [26]

2.6 LVADs and Artificial Heart Systems

LVADs are used to support the pumping of the weak left ventricle to increase the blood flow to the body. LVADs enable the weak ventricle to do the work of heart without completely removing. However, the total artificial heart systems are used to treat patients with irreversible left or right ventricular failure by a complete heart replacement. The key companies driving the development of LVADs and TAHs include Abiomed, [38]Thoratec, [39, 40]BerlinHeart, [41, 42]MicroMed, [43]HeartWare,[44-51] and LionHeart. [52] The power requirements of these pumps are approximately from 3 to 30W. At present, percutaneous leads power the majority of these pumps due to their high power consumption. However, there is massive interest in the implementation of a wireless power supply solution because of the increased incidences of driveline related skin infections. Therefore, this paper focuses on identifying the gap in designing a TET system (Figure 1) for high power LVADs and TAHs. The review of key commercial LVAD and TAH systems is given below in the next section.

3. KEY LVADs AND TAHs

The review of key commercial LVADs and TAHs is presented below.

3.1 A bioMed's Artificial Heart System

A bioMed's artificial heart system is shown in Figure 2. [38] It is the first fully -implantable total artificial system developed by AbioCor. Development of this system is done for end-stage heart failure patients whose hearts have left and right ventricular failure and for whom surgery or medical treatment is insufficient. [53-55] AbioCor is powered using the

TET system. This system consist of internal and external coils which are used to wirelessly transfers power across the skin. Its external battery packs can power it for 4 hours; whereas, with the help of internal battery patient can move freely for an hour without the help of external battery. [38] Efficiency of the AbioCor system ranging from 68% to 72% for coil separation between 3 to 10mm with output current ranging from 1.5 to 3.6A.

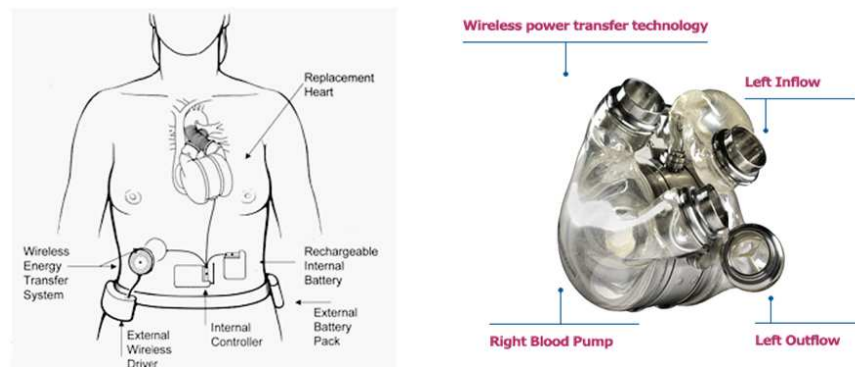


Figure 2: Abicor Artificial Heart System [38]

3.2 Heartmate II LVAD System

Heartmate II is shown in Figure 3 and is also known Thoratec LVAD system after its developer Thoratec Ltd.^[56-63] It is a rotary ventricular assist system consists of a blood pump, power source and a driver system (Figure 3a).^[56-63]

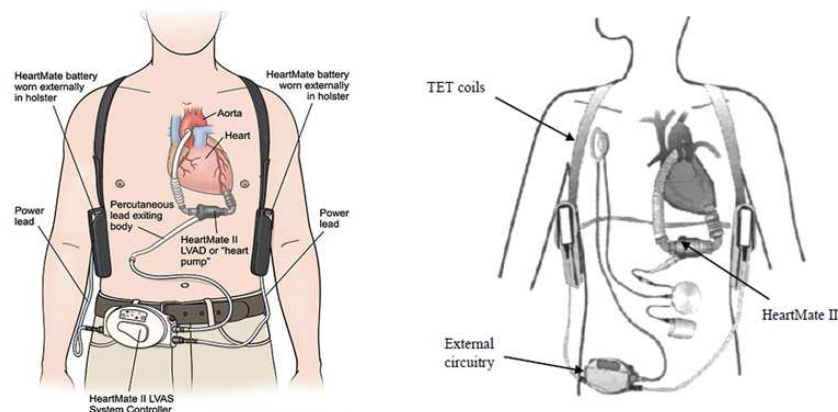


Figure 3: Heart Mate II System Powered using (a) Percutaneous Lead and (b) TET System [56, 57]

The pump can produce a stroke volume of up to 83 mL and a flow of up to 11.5 L/min (Figure 3a). The system can be charged either by a power supply from mains or up to 2 to 4 hours using the rechargeable batteries under normal operating conditions.^[56-63] It can also be powered by wireless power supply using the TET system (Figure 3b).^[58-63] The diameter and height of the secondary coil are 73mm and 19mm respectively.

3.3 Berlin Heart LVAD System

This system is an implantable LVAD.[41, 42] It is shown in Figure 4 and is a flow pump with a free-floating, active magnetic bearing. An external controller is used to operate the device. Percutaneous leads are used to connect the controller with the pump. In principle, blood flowing through heart flows into INCOR pump and then passes through the inlet guide vane. [41] A set of the fully charged external battery can operate up to 10 to 12 hours. Operating speed of the pump is approximately 5000- 10000 rpm and its power consumption is about 3 to 4 W. [41, 42] Weight of pump is 200g

with the volume of 81ml and length and outer diameter are 120mm and 30mm respectively.



Figure 4: Berlin Heart LVAD system [41]

3.4 Heart Ware HVAD Pump

It is shown in Figure 5 and is a left ventricular assist device. ^[49] Its function is to pump blood-- from the left side of the heart to aorta and then to the other parts of the body. The blood exits the pump in a continuous flow. The HVAD is run by an external controller through a percutaneous lead. Driveline connects the HVAD and controller which pass from the skin on the patient's upper abdomen. ^[44, 45, 49] This controller runs the pump and provides an audible alarm and text messages for help in managing the function of the system. A controller can be charged by using batteries and electricity from a wall or car outlet. ^[49]



Figure 5: HeartWare Ventricular Assist System Pump in Pericardial Space [49]

3.5 Jarvik 2000 FlowMaker LVAD

The Jarvik 2000 VAD is shown in Figure 6. It is an LVAD and has titanium housing-containing a rotating impeller. Silicon carbide mechanical bearings hold and magnetically drive the impeller. ^[64-68] The Jarvik 2000 is implanted in the thoracic space and within the pericardium, which surrounds the heart. ^[64-68] It is powered by an external device using a percutaneous lead, which exits through the abdominal wall. Additional length and flexibility can be provided by connecting this lead to an external extension cable. A lithium-ion battery pack is used to run the controllers which can power the Jarvik pump for up to 12 hours. ^[64-68] This lithium-ion pack is connected to the controller by Y cable. With the help of this y cable, the battery can be changed without stopping the pump.

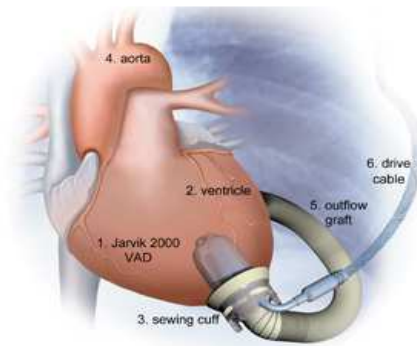


Figure 6: Jarvik 2000 flow maker LVAD [64-68]

3.6 MicroMed LVAD System

The MicroMedDeBakey VAD system is shown in Figure 7. It consists of a controller, an external battery with charger pack and a medical data acquisition system.^[43] A direct current motor stator is used to drive the pump. The pump impeller consists of six blades and each blade contains eight magnets that are very tightly sealed so that air cannot pass from them.^[43] The pump size and weight are 30 x 76mm and 95g respectively. It can pump up to 10 liters per minute. The rotational speed of the impeller is from 7500 to 12000 rpm.^[43] Two 12 V rechargeable batteries are used to charge the pump. Each battery can power the pump for up to 2.5 to 4 hours. Power requirements of the pump depend on the pump speed and it can vary from 5 to 12 W.^[43]

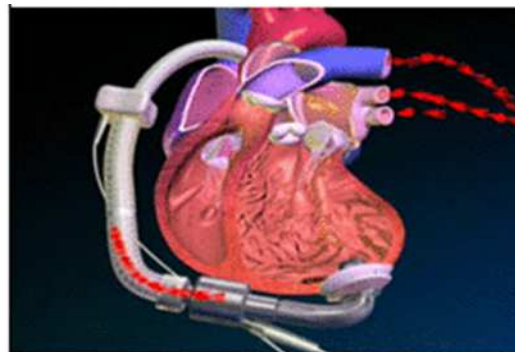


Figure 7: MicroMed DeBakey VAD System [43]

3.7. Lion Heart

The Lion Heart is an implantable LVAD which uses TET to power the pump.^[52] The maximum outflow of the pump is 8 L/min, and the power requirement for operation is 12 V dc. The minimum power requirement of LionHeart system is 14W and it contains an internal rechargeable battery which can work up to 20 minutes without a TET system.^[52] The diameter of the implanted coil is approximately 73 mm and its weight is about 137 g.^[52] The external coil is approximately 125 mm in diameter as shown in Figure 8. The external coil is secured over the internal coil using a belt or a traumatic skin tape adhesive.



Figure 8: LionHeart TET System [52]

From the description of above LVADs and TAHs, it is clear that we can differentiate the operating conditions of TET on the bases of power requirements and separations between the internal and external coils, depending on its application. Table 1 shows the summary of power requirements and the separation between primary and secondary coils in recently designed TET systems.

Table 1: Coil Separations and Power Requirements of TET Systems used in Medical Implants

Medical Implants	Separations Between the Coils (mm)	Power Requirements (W)
Cochlear Implants	3 - 10	0.01
Cardiac Pacemaker	5 - 15	30 μ -100 μ
Implantable Telemetry Unit	35 - 100	0.1
Retinal Prosthetic Device	7 - 5	0.25
Functional Electrical Simulator	5 -15	0.1 - 1
LVAD	10 - 20	3 - 30
TAH	10 - 20	3 - 30

Artificial hearts needed the highest power for their operation. The separation between primary and secondary coils in TET systems is the thickness of the patient's skin which is approximately 10-20 mm. Further, Table 2 gives the power requirements and flow outputs of existing LVAD and TAH systems.

Table 2: Coil Separations and Power Requirements of TET Systems used in Medical Implants

Pump manufacturer – Heart Pump name	Pump Type	Power Consumption (Watts)	Pump Flow (L/min)	Power Source
Berlin Heart - INCOR	Axial flow	3 – 4	6	Cable
Thoratec – HeartMate II	Centrifugal	20	11.5	Cable
MicroMed – DeBakey VAD	Axial Flow	12	12	Cable
LionHeart – Arrow	Electromechanical	14	8	TET
AbioMed – AbioCor	TAH	25	4-8	TET
Terumo-T-ILVAS	Centrifugal	13	5	Cable
WorldHeart– HeartSaver	Electrohydraulic	30	11	Cable

A massive variation in power requirements can be observed depending on the pump design. It is because the pump flow rate varies according to the flow of blood and results in power variations required by the pump. Power

consumption of the pump is high if the blood flow rate is large.

4. KEY CHALLENGES ASSOCIATED WITH TET SYSTEMS

TET systems have several advantages as compared to implantable batteries and percutaneous leads; however, there are various challenges in designing these systems. These are mentioned below:

4.1. Efficiency

TET systems which have low power requirements, like cardiac pacemaker, have very low efficiency of around 20 to 60%. Overall efficiency is not important in these systems because power wastage is very low ($<1W$). [24] However, power efficiency is an important factor in TET systems which require high power, because even at high power efficiencies of up to 80%, there is a power loss of several watts. [18, 25] This power loss can result in heating of the implanted device. [18, 25] this excessive heating in the implant can damage the surrounding tissues. [69]

4.2 Tolerance to Misalignment

The power transfer capability of TET systems highly depends on the coupling of coils. Even a small change in position of primary and secondary coils can result in large variations in the coupling between the coils. [70-73] It is due to the change in position of coils in implants because in medical applications one coil is outside the body and the second coil is inside the body and variations in orientation is unavoidable. It might be caused by variations in surgical placement, patient's posture change and changes in the patient's skin surface near the primary coil (e. g. due to the growth of patient). There are two ways widely adopted to deal with the misalignment of coils. The first approach is to minimize variations by making a consistent arrangement in coil design For example, in LionHeart TET system, the patient's skin is protruded to assist with the identification and positioning of the primary coil on the skin surface. [52]

4.3 Implant Size

In principle, the smallest implant size is preferred for the purpose of reducing infections risk, ease of deployment and increasing the patient comfort. [74-76] In practice, size reduction may be limited by many factors such as power rating, temperature range, and operating frequency. Thus, depending on the type of TET system and position of the implant, the coil should have an appropriate size. [74-76] for example, a cochlear implant has a lesser number of turns in a coil because this implant is located in the ear where variations in coupling are less and its power requirement is only 10 mW. [24] However an artificial heart requires 10-30 W power and a coil with a lesser number of turns will have large currents flowing through it; thus generates a large amount of heat in the implant.

4.4 Power Supplies

The power requirement of implanted devices highly depends on the applications of the implants. For example, a cochlear implant, it is used for hearing purpose and consumes only 10mW power [77] The approximate power requirement for Implantable artificial hearts is in the region of 3 to 30 W. [25] In addition, their physical design varies considerably depending on their application and area of use.

4.5 Temperature

In high power implants, the coils get heated due to the high current flowing through them. [18] This causes discomfort to the patient and may even damage the tissue surrounding the coils and/or the implant. The tolerance of

temperature fluctuation depends upon the physiological variations in patients and the location of implants. These fluctuations become cumbersome in TET systems with poor coupling, impedance mismatch, and efficiency. Therefore, the TET system for high power implants needs to be designed to sense and stabilize temperature fluctuations.

4.6 Implantable Batteries

Implantable batteries are designed to provide a constant stable output voltage, fully sealed and ideally maintenance free. [19, 26, 78] Use of batteries depends on the time duration of device functioning because batteries have a finite life span. Implantable batteries are used only in devices which have low power consumption applications, where power requirement is of 1 mW to 1 W range. [19, 26, 78] When the battery is near exhaustion, the implant needs to be surgically removed, which is expensive in terms of costs, discomfort, and risks to patients. Rechargeable batteries can provide a suitable and convenient power source and a suitable method of recharging them can be implemented

For designing these batteries, the various important performance parameters are temperature, voltage, duty cycle, operating life, reliability, safety, internal resistance and power needed (watts/kg). [19, 26, 78] Essential factors in selecting a battery for medical applications are: minimum and maximum voltage; Initial, average, and maximum discharge current; Continuous operation; service life; and good performance in various conditions (temperatures, duty cycles, etc.). Lithium batteries are mostly used batteries in implantable devices. [31]

From the above-made discussion, it is clear that TET systems can be used to run high power implants. This will provide wide-spread adaptability and eliminates the infection risks of a percutaneous lead. However, for its efficient operation, there is a high requirement of progress in both tolerances to variation in the coupling, temperature maintenance improvement, and reduced physical size.

5. CONCLUSIONS AND FUTURE RESEARCH DIRECTIONS

This paper presented a discussion on using transcutaneous energy transfer for high power medical implants: LVADs and TAHs. For this purpose, several commercial LVADs and TAHs are described along with their power requirements. For example AbioCorAbioMed, Thoratec Heartmate II, Berlin Heart INCOR, HeartWare, Jarvik 2000, MicroMed and LionHeart. From the discussion, it is found that the power requirement of these pumps varies from 3 to 30W and flow rate from 4 to 12 liter/min. Therefore, these devices are rated high power (>3W) in medical implants industry. Thus, a percutaneous lead conventionally powers these devices. This lead starts from the internal pump and goes through the skin to an external dc power source. The area of contact of driveline with the abdominal wall represents a source of potential infections. Therefore, there is massive interest in the design of a wireless power supply system. Thus, this paper presented the principle of the TET system, in which the power is transmitted using a transcutaneous transformer built up of two coils separated by a patient's skin.

To drive this transformer, the TET system contains a primary power converter to generate a time-varying magnetic field from the external dc power source. This high-frequency electrical energy is transmitted to the secondary coil, implanted inside the patient. This induces a voltage in the secondary coil, which is rectified to dc voltage and supplied to load such as LVAD and TAH. In the TET system, the dc power source is placed outside the body. Therefore, the TET power system is capable of long term (theoretically infinite) operation at high power outputs. In this way, these systems eliminate the risk of infection caused by percutaneous leads and remove the need for repetitive surgeries as needed with non-rechargeable batteries. However, depending on the pump design, the power requirements can massively vary. It is

because the pump flow rates vary according to the blood flow and thus results in variation in power required by the pump. Larger flow rates correspond to higher power requirements. Therefore, the efficiency and reliability of the TET system for high power implants need to be very high.

For a TET system with high efficiency, high magnetic coupling between the coils is required. This will result in low losses, high power transfer, and low tissue heat generation. In addition, the system needs to be operated at resonance frequency to match the impedance. From the discussion made, TET systems found to have a number of challenges, such as efficiency, tolerance to misalignment, implant size, implantable batteries, impedance mismatch, heating of coils and continuous power supply. This becomes cumbersome for high power devices, where even at high power efficiencies of over 80%, several watts of power is lost. This high power loss can cause heating of the implanted circuit and can damage the surrounding tissues. Presently there is no fixed temperature at which tissue damage can occur. It is because the tissue damage can be caused by many factors such as environmental temperature, physiological variations in patients and also the location of implants. At high powers, where continuous uninterrupted power is required, the efficiency is even more important as the capability of the body to dissipate heat is difficult to increase or control. In addition, an inefficient system will also require the patient to carry a large external battery or charge more frequently. Therefore, a high efficiency, tolerance to misalignment of coils and thermal management is of prime importance for a TET system for high power implants. Therefore, the future direction is to design a TET system with performance criteria at a level appropriate for powering LVADs & TAHs, which provides high efficiency, advancement in both tolerances to variation in the coupling, improved temperature maintenance, and reduced physical size.

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